SAB Review Charge Questions
July 3, 2003 - REVISED

This document conveys a set of specific charge questions which EPA respectfully requests that the SAB Council consider during its review of the draft analytical blueprint for the upcoming section 812 benefit-cost study of the Clean Air Act. The charge questions are organized by blueprint chapter or appendix. The first question posed for each chapter or appendix is intended to serve as a general charge question consistent with the statutory criteria for Council review of the section 812 studies. Additional, more detailed charge questions are also conveyed for most chapters and appendices.

These supplemental charge questions reflect EPA's desire to obtain specific and detailed advice from the Council on particular analytical issues.

Chapter 1: Project Goals and Analytical Sequence

1. Does the Council support the study goals, general analytical framework, disaggregation plan, analytical sequence, and general analytical refinements defined in chapter 1? If there are particular elements of these plans which the Council does not support, are there alternatives the Council recommends?

Chapter 2: Scenario Development

2. Does the Council support the choices for analytical scenarios defined in chapter 2? Are there alternative or additional scenarios the Council recommends EPA consider for inclusion in the analysis?

3. Does the Council support the alternative compliance pathway estimation and comparison methodology described in chapter 2, including the specification of alternative compliance pathways which may not reflect precisely constant emissions or air quality outcomes between scenarios due (primarily) to the non-continuous nature and interaction effects of emission control options?

Chapter 3: Emissions Estimation

4. Does the Council support the plans for estimating, evaluating, and reporting emissions changes as defined in chapter 3? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

5. Chapter 3 of the analytical plan describes several alternative approaches considered by EPA for estimating non-EGU emissions growth rates. These options reflect different relative emphasis between two conflicting analytical objectives: (1) extensive refinement of the geographically differentiated, source-specific economic activity growth estimates

embedded in EGAS 4.0, and (2) maintaining the current project schedule and budget. EPA plans to use "approach #4", a compromise option which targets the most important source categories for potential refinement. Does the Council support the initial plan to use "approach #4"? If the Council does not support the use of approach #4, are there other approaches –including either the approaches described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

6. Some state-supplied emissions data incorporated in the 1999 National Emissions Inventory (NEI) –the core emissions inventory for this analysis– incorporate different emissions factors from those used in MOBILE6, the mobile source emissions model EPA plans to use for estimating emissions changes between scenarios. Of particular importance, some of the emissions factors embedded in California's EMFAC model may be significantly different from factors used in MOBILE6. EPA considered three options for estimating emissions changes in California, which are described in chapter 3. EPA plans to implement option #3 based on the belief that the emission factors embedded by California in its EMFAC model may be more accurate for their particular state than the factors incorporated in MOBILE6. Does the Council support the plan to implement option #3? If the Council does not support the adoption of option #3, are there other options –including either the options described in chapter 3 or others identified by the Council– which the Council suggests EPA consider?

Chapter 4: Cost Estimates

7. Does the Council support the plans for estimating, evaluating, and reporting compliance costs described in chapter 4? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

8. EPA seeks advice from the Council concerning the choice of Computable General Equilibrium (CGE) model which EPA intends to use as a post-processor to gauge the general equilibrium effects of the various control scenarios. In the first 812 study –the retrospective– EPA used the Jorgenson/Wilcoxen model to gauge the general equilibrium effects of returning to the economy the reported compliance expenditures which formed the basis of the retrospective study direct cost estimates. This model has since been refined in many ways, and EPA considers both the Jorgenson/Wilcoxen/Ho and AMIGA to be acceptable tools. Although a final decision on model choice can be deferred until later in the analysis, EPA has tentative plans to use the AMIGA model because of its greater sectoral disaggregation, better industrial sector matching with CAA-affected industries, richer representation of relevant production and consumption technologies, and better model validation opportunities due to its use of open code. However, AMIGA is limited given its inability to deal with dynamics over time. Does the Council support the current, tentative plan to use the AMIGA model for this purpose? If not, are there alternative model choices or selection criteria the Council recommends?

9. In the two previous 812 studies, the primary cost estimates reflected use of a 5 percent real discount rate, which an earlier Council endorsed as a reasonable compromise between a 3 percent real rate considered by EPA to be an appropriate estimate of the consumption rate of interest or rate of social time preference and a 7 percent rate, OMB's estimate of the opportunity cost of capital. Limited sensitivity testing was also conducted in the previous 812 studies by substituting 3 and 7 percent rates to annualize the benefit and cost streams. EPA's new Economics Guidelines (peer-reviewed by the SAB EEAC) call for using both a 3 and a 7 percent rate. A recent draft of new OMB economic guidelines suggests providing results based on both 3 and 7 percent discount rates, while also acknowledging the need for further efforts to refine analytical policies for discounting methods and rates. EPA plans on following both sets of Guideline documents by using both 3 and 7 percent in our core analyses. It is true that this will require presentation of two sets of results – one based on each rate. This may not be necessary given the expected insensitivity of the overall results to the discount rate assumption. Does the Council support this approach? If not, are there alternative rates, discounting concepts, methods, or results presentation approaches the Council recommends?

Chapter 5: Air Quality Modeling

10. Does the Council support the plans described in chapter 5 for estimating, evaluating, and reporting air quality changes associated with the analytical scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

Chapter 6: Human Health Effects Estimation

11. Does the Council support the plans described in chapter 6 for estimating, evaluating, and reporting changes in health effect outcomes between scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

12. EPA seeks advice from the Council regarding the technical and scientific merits of incorporating several new or revised endpoint treatments in the current analysis. These health effect endpoints include:

    a. Premature mortality from particulate matter in adults 30 and over, PM (Krewski et al., 2000);

    b. A PM premature mortality supplemental calculation for adults 30 and over using the Pope 2002 ACS follow-up study with regional controls;

    c. Hospital admissions for all cardiovascular causes in adults 20-64, PM (Moolgavkar et al., 2000);

d. ER visits for asthma in children 0-18, PM (Norris et al., 1999);

e. Non-fatal heart attacks, adults over 30, PM (Peters et al., 2001);

f. School loss days, Ozone (Gilliland et al., 2001; Chen et al., 2000);

g. Hospital admissions for all respiratory causes in children under 2, Ozone (Burnett et al., 2001); and,

h. Revised sources for concentration-response functions for hospital admission for pneumonia, COPD, and total cardiovascular: Samet et al., 2000 (a PM10 study), to Lippmann et al., 2000 and Moolgavkar, 2000 (PM2.5 studies).

13. EPA seeks advice from the Council regarding the merits of applying updated data for baseline health effect incidences, prevalence rates, and other population characteristics as described in chapter 6. These updated incidence/prevalence data include:

a. Updated county-level mortality rates (all-cause, non-accidental, cardiopulmonary, lung cancer, COPD) from 1994-1996 to 1996-1998 using the CDC Wonder database;

b. Updated hospitalization rates from 1994 to 1999 and switched from national rates to regional rates using 1999 National Hospital Discharge Survey results;

c. Developed regional emergency room visit rates using results of the 2000 National Hospital Ambulatory Medical Care Survey;

d. Updated prevalence of asthma and chronic bronchitis to 1999 using results of the National Health Interview Survey (HIS), as reported by the American Lung Association (ALA), 2002;

e. Developed non-fatal heart attack incidence rates based on National Hospital Discharge Survey results;

f. Updated the national acute bronchitis incidence rate using HIS data as reported in ALA, 2002, Table 11;

g. Updated the work loss days rate using the 1996 HIS data, as reported in Adams, et al. 1999, Table 41;

h. Developed school absence rates using data from the National Center for Education Statistics and the 1996 HIS, as reported in Adams, et al., 1999, Table 46.

1. Developed baseline incidence rates for respiratory symptoms in asthmatics, based on epidemiological studies (Ostro et al. 2001; Vedal et al. 1998; Yu et al; 2000; McConnell et al., 1999; Pope et al., 1991).

14. EPA plans to initiate an expert elicitation process to develop a probability-based method for estimating changes in incidence of PM-related premature mortality. Plans for this expert elicitation are described in chapter 9 of this blueprint, and a separate charge question below requests advice from the Council pertaining to the merits of the design of this expert elicitation. EPA recognizes, however, the possibility that this expert elicitation process may not be fully successful and/or may not be completed in time to support the current 812 analysis. Therefore, in order to facilitate effective planning and execution of the early analytical steps which provide inputs to the concentration-response calculations, EPA seeks advice from the Council regarding the scientific merits of alternative methods for estimating the incidences of PM-related premature mortality, including advice pertaining to the most scientifically defensible choices for the following specific factors:

    a. Use of cohort mortality studies, daily mortality studies, or some combination of the two types of studies

    b. Selection of specific studies for estimating long-term and/or short-term mortality effects

    c. Methods for addressing –either quantitatively or qualitatively– uncertain factors associated with the relevant concentration-response function(s), including

        i. Shape of the PM mortality C-R function (e.g., existence of a threshold),
        ii. PM causality,
        iii. PM component relative toxicity, and
        iv. PM mortality effect cessation lag structure
        v. Cause of death and underlying health conditions for individuals dying prematurely due to chronic and/or short term exposures to particulate matter
        vi. The use of ambient measures of exposure for estimating chronic health effects, given recent research reviewed in the NAS (2002) report that questions the implications of using ambient measures in cohort studies

15. EPA estimates of benefit from particulate control may underestimate the impact of nonfatal cardiopulmonary events on premature mortality and life expectancy. For the base analyses, which rely on cohort evidence, the limited follow-up periods for the cohorts may not fully capture the impacts of nonfatal cardiovascular events on premature mortality later in life. For the alternative analyses –including cost-effectiveness analyses– which rely more on acute studies and life-expectancy loss, the years of life are estimated only for fatal events. Yet nonfatal events such as myocardial infarction reduce a person's life expectancy by a substantial percentage.

    a. Do you agree that EPA, in the 812 analyses, should adjust benefit estimates to account for the mortality effects of non-fatal cardiovascular and respiratory events?

b. What medical studies and mathematical models of disease might be useful to review or use if EPA moves in this direction?

c. When the nonfatal events are valued in economic terms, should EPA assume that the published unit values for morbidity already account for the life-expectancy loss or should an explicit effort be made to monetize the resulting longevity losses?

16. In recent EPA rulemakings, EPA's "base estimate" of benefit from PM control has been based on cohort epidemiological studies that characterize the chronic effects of pollution exposure on premature death as well as capturing a fraction of acute premature mortality effects. If these chronic effects occur only after repeated, long-term exposures, there could be a substantial latency period and associated cessation lag. As such, a proper benefits analysis must consider any time delay between reductions in exposure and reductions in mortality rates. For the acute effects, such as those considered in EPA's alternative benefit analyses, the delays between elevated exposure and death are short (less than two months), and thus time-preference adjustments are not necessary.

a. In the previous 812 analysis and in recent rulemakings, EPA assumed a weighted 5-year time course of benefits in which 25% of the PM-related mortality benefits were assumed to occur in the first and second year, and 16.7% were assumed to occur in each of the remaining 3 years. Although this procedure was endorsed by SAB, the recent NAS report (2002) found "little justification" for a 5-year time course and recommended that a range of assumptions be made with associated probabilities for their plausibility. Do you agree with the NAS report that EPA should no longer use the deterministic, 5-year time course?

b. One alternative EPA is considering is to use a range of lag structures from 0 to 20-30 years, with the latter mentioned by NAS in reference to the Nyberg et al PM lung cancer study, with 10 or 15 years selected as the mid-point value until more definitive information becomes available. If this simple approach is used, should it be applied to the entire mortality association characterized in the cohort studies, or only to the difference between the larger mortality effect characterized in the cohort studies and the somewhat smaller effect found in the time series studies of acute exposure? Should judgmental probabilities be applied to different lags, as suggested by NAS?

c. Another option under consideration is to construct a 3-parameter Weibull probability distribution for the population mean duration of the PM mortality cessation lag. The Weibull distribution is commonly used to represent probabilities based on expert judgment, with the 3-parameter version allowing the shaping of the probability density function to match expected low, most likely, and expected high values. EPA is still considering appropriate values for the low, most likely, and expected high values –and therefore for the Weibull shape and location parameters– and EPA is interested in any advice the Council wishes to provide pertaining to the merits of this approach and/or reasonable values for the probability distribution.

17. In support of Clear Skies and several recent rule makings the Agency has presented an Alternative Estimate of benefits as well as the Base Estimate. EPA developed the Alternative Estimate as an interim approach until the Agency completes a formal probabilistic analysis of benefits. NAS (2002) reinforced the need for a probabilistic analysis. The Alternative Estimate is not intended as a substitute method and needs to be considered in conjunction with the Base Estimate. Presentation of Base and Alternative estimates in the 812 Report may not be necessary if the probability analysis planned for the 812 Report is successful. While the Base Estimate assumes that acute and chronic mortality effects are causally related to pollution exposure, the Alternative Estimate assumes only acute effects occur or that any chronic effects are smaller in size than assumed in the Base Estimate. The Council's advice is sought on the following matters:

    a. It has been noted by some particle scientists that the size of estimates based on time series studies that incorporate a distributed lag model, accounting for effects of 30 to 60 days after elevated exposure, may be similar in size to some interpretations of the results from the cohort studies. Does the Council agree that it is a reasonable alternative to use an estimate of the concentration-response function consistent with this view? If the Council agrees with the assumption, can it suggest an improved approach for use in an Alternative Estimate? The agency also seeks advice on appropriate bounds for a sensitivity analysis of the mortality estimate to be used in support of the Alternative Estimate.

    b. An assumption that a specific proportion of the PM-related premature mortality incidences are incurred by people with pre-existing Chronic Obstructive Pulmonary Disease (COPD) and that these incidences are associated with a loss of six months of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

    c. An assumption that the non-COPD incidences of PM-related premature mortality are associated with a loss of five years of life, regardless of age at death. If these values are not valid, what values would be more appropriate? Do you recommend a sensitivity analysis of 1 to 14 years (with the latter based on standard life tables), as included in the draft regulatory impact analysis of the proposed Nonroad diesel rule?

    d. Additional quantified and/or monetized effects are those presented as sensitivity analyses to the primary estimates or in addition to the primary estimates, but not included in the primary estimate of total monetized benefits. While no causal mechanism has been identified for chronic asthma and ozone exposure, there is suggestive epidemiological evidence.

i. Two studies suggest a statistical association between ozone and new onset asthma for two specific groups: children who spend a lot of time exercising outdoors and non-smoking men. We seek SAB comment on our approach to quantifying new onset asthma in the sensitivity analyses.

ii. Premature mortality associated with ozone is not currently separately included in the primary analysis because the epidemiological evidence is not consistent. We seek SAB comment on our approach to quantifying ozone mortality in the sensitivity analyses.

iii. Does the Council agree that there is enough data to support a separate set of health impacts assessment for asthmatics? If so, does the approach proposed by the Agency address the uncertainty in the literature?

Chapter 7: Ecological Effects

18. Does the Council support the plans described in chapter 7 for (a) qualitative characterization of the ecological effects of Clean Air Act-related air pollutants, (b) an expanded literature review, and (c) a quantitative, ecosystem-level case study of ecological service flow benefits? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

19. Initial plans described in chapter 7 reflect a preliminary EPA decision to base the ecological benefits case study on Waquoit Bay in Massachusetts. Does the Council support these plans? If the Council does not support these specific plans, are there alternative case study designs the Council recommends?

20. Does the Council support the plan for a feasibility analysis for a hedonic property study for valuing the effects of nitrogen deposition/eutrophication effects in the Chesapeake Bay region, with the idea that these results might complement the Waquoit Bay analysis?

Chapter 8: Economic Valuation

21. Does the Council support the plans described in chapter 8 for economic valuation of changes in outcomes between the scenarios? If there are particular elements of these plans which the Council does not support, are there alternative data or methods the Council recommends?

22. EPA's current analytic blueprint calls for an expert-judgment project on VSL determination that would produce a probability distribution over the range of possible VSL values for use in the 812 project. EPA is not sure how much priority to give to this project. A much simpler alternative would be for EPA to specify a plausible range of VSL values. One option would be to use a range bounded by $1 million (based roughly on the lower bound of the interquartile range from the Mrozek-Taylor meta-analysis) and $10 million (based roughly on the upper bound of the interquartile range of the Viscusi-

Aldy meta-analysis. This range would match that reflected in EPA's sensitivity analysis of the alternative benefit estimate for the off-road diesel rulemaking. The range would then be characterized using a normal, half-cosine, uniform or triangular distribution over that range of VSL values. EPA would then ask this Committee to review this distribution. This approach could be done relatively quickly, based on the reviews and meta-analyses commissioned to date, and would allow a formal probability analysis to proceed, without suggesting that the Agency is trying to bring more precision to this issue than is warranted by the available science.

23. Pursuant to SAB Council advice from the review of the first draft analytical blueprint, EPA reviewed a number of meta-analyses –either completed or underway– developed to provide estimates for the value of statistical life (VSL) to be applied in the current study. EPA plans to consult with the Council (and coordinate this consultation with the EEAC) on how best to incorporate information from the Kochi et al (2002) meta-analysis, other published meta-analyses [Mrozek and Taylor and Viscusi and Aldy], and recent published research to develop estimates of VSL for use in this study. In addition, EPA plans to implement two particular adjustments to the core VSL values: discounting of lagged effects and longitudinal adjustment to reflect changes in aggregate income. Does the Council support these plans, including the specific plans for the adjustments described in chapter 8? If the Council does not support these plans, are there alternative data or methods the Council recommends?

24. For the 812 Report, EPA has decided to perform a cost-effectiveness analysis of the Clean Air Act provisions using quality-adjusted life years as the measure of effectiveness. This is the standard approach used in medicine and public health and this type of analysis has previously been recommended by the SAB. Moreover, the recent NAS Report (2002) on benefits analysis discussed how this method could be applied to the health gains from air pollution control.

    a. Do you agree that QALYs are the most appropriate measure of effectiveness for this type of analysis? Would you suggest any alternative measures to replace or supplement the QALY measure? (This question relates to effectiveness measures, not monetary benefit measures as used in benefit-cost analysis).

    b. OMB has suggested that EPA plan a workshop with clinicians, social scientists, decision analysts and economists to examine how the specific diseases and health effects in the 812 Report should be handled with respect to longevity impact and health-related preference. Participants would have knowledge of the relevant clinical conditions, the related health preference studies, and the stated-preference literature in economics. The recent RFF conference has laid the groundwork for this type of workshop. Is there a superior approach to making sure that the CEA-QALY project is executed in a technically competent fashion and that the details of the work receive in-depth technical input in addition to the broad oversight provided by this Committee?

c. Does the Council support the specific plans for QALY-based cost-effectiveness described in the current draft blueprint? If the Council does not support specific elements of these plans, are the alternative data, methods, or results presentation approaches which the Council recommends?

25. EPA plans to use updated unit values for a number of morbidity effects, as described in chapter 8. Of particular note, EPA plans to rely on a study by Dickie and Ulery (2002) to provide heretofore unavailable estimates of parental willingness to pay to avoid respiratory symptoms in their children. This study is not yet published and has limitations concerning response rate and sample representativeness; however, EPA expects the study to be published prior to completion of the economic valuation phase of this analysis. Does the Council support the application of unit values from this study, contingent on its acceptance for publication in a peer-reviewed journal? If the Council does not support reliance on this study, are there other data or methods for valuation of respiratory symptoms in children which the Council recommends?

Chapter 9: Uncertainty Analysis

26. Does the Council support the plans described in chapter 9 for estimating and reporting uncertainty associated with the benefit and cost estimates developed for this study? If there are particular elements of these plans which the Council does not support, are there alternative data, models, or methods the Council recommends?

27. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the compliance cost estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in cost estimates for this analysis which the Council recommends?

28. Does the Council support the plans described in chapter 9 for the pilot project to develop probability-based estimates for uncertainty in the emissions and air quality modeling estimates? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying uncertainty in emissions and/or air quality concentration estimates for this analysis which the Council recommends?

29. Does the Council support the plans described in chapter 9 for the expert elicitation pilot project to develop a probability-based PM2.5 C-R function for premature mortality, including in particular the elicitation process design? If the Council does not support the expert elicitation pilot project, or any particular aspect of its design, are there alternative approaches the Council recommends for estimating PM-related mortality benefits for this analysis, including in particular a probabilistic distribution for the C-R function to reflect uncertainty in the overall C-R function and/or its components?

30. EPA plans to develop estimates of an independent mortality effect associated with ozone, as described in chapter 9. Does the Council support the use of the most recent literature on the relationship between short-term ozone exposure and daily death rates, specifically that portion of the literature describing models which control for potential confounding by PM2.5? Does the Council agree with the use of that literature as the basis for deriving quantified estimates of an independent mortality impact associated with ozone, especially in scenarios where short-term PM2.5 mortality estimates are used as the basis for quantifying PM mortality related benefits? Does the Council support the plans described in chapter 9 for the pilot project to use this literature to develop estimates of the ozone-related premature mortality C-R function using the three alternative meta-analytic approaches? If the Council does not support this pilot project, or any particular aspect of its design, are there alternative approaches to quantifying ozone-related premature mortality which the Council recommends?

31. EPA plans to work with the Council and the EEAC to develop revised guidance on appropriate VSL measures. We hope to include the Kochi et al (2002) meta-analysis, other recent meta-analysis, recent publications, and the 3 literature reviews sponsored by EPA.(a separate charge question pertaining to this element of EPA's VSL plan is presented below). In addition, EPA plans to conduct a follow-on meta-regression analysis of the existing VSL literature to provide insight into the systematic impacts of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL. Does the Council support the plans described in chapter 9 for conducting this meta-regression analysis? If the Council does not support this analysis or any particular aspect of its design, are there alternative approaches which the Council recommends for quantifying the impact of study design attributes, risk characteristics, and population attributes on the mean and variance of VSL?

Chapter 10: Data Quality and Intermediate Data Products

32. Does the Council support the plans described in chapter 10 for evaluating the quality of data inputs and analytical outputs associated with this study, including the planned publication of intermediate data products and comparison of intermediate and final results with other data or estimates? If the Council does not support these plans, are there alternative approaches, intermediate data products, data or model comparisons, or other data quality criteria the Council recommends? Please consider EPA's Information Quality Guidelines in this regard.

Chapter 11: Results Aggregation and Reporting

33. Does the Council support the plans described in Chapter 11 for the aggregation and presentation of analytical results from this study? If the Council does not support these

plans, are there alternative approaches, aggregation methods, results presentation techniques, or other tools the Council recommends?

Appendix D: Stratospheric Ozone Analysis

34. Does the Council support the plans describe in Appendix D for updating the estimated costs and benefits of Title VI programs? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

Appendix E: Air Toxics Case Study

35. Does the Council support the plans described in Appendix E for the benzene case study, including the planned specific data, models, and methods, and the ways in which these elements have been integrated? If the Council does not support these plans, are there alternative data, models, or methods the Council recommends?

36. A cessation lag for benzene-induced leukemia is difficult to estimate and model precisely due to data limitations, and EPA plans to incorporate a five-year cessation lag as an approximation based on available data on the latency period of leukemia and on the exposure lags used in risk models for the Pliofilm cohort (Crump, 1994 and Silver et al., 2002). Does the SAB support adoption of this assumed cessation lag? If the Council does not support the assumed five-year cessation lag, are there alternative lag structures or approaches the Council recommends?

Appendix H: Meta-analysis of VSL

37. Does the Council support including the Kochi et al. (2002) meta-analysis as part of a the larger data base of studies to derive an estimate for the value of avoided premature mortality attributable to air pollution? Are there additional data, models, or studies the Council recommends? Does the SAB think that EPA should include Kochi et al. 2003 if not accepted for publication in a peer reviewed journal by the time the final 812 report is completed?